

## PATENT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents  
United States Patent and Trademark  
Office  
Box PCT  
Washington, D.C.20231  
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

|  |  |
|--|--|
| Date of mailing (day/month/year)<br>18 November 1999 (18.11.99)        |  |
| International application No.<br>PCT/DK99/00108                        | Applicant's or agent's file reference<br>21274PC1          |
| International filing date (day/month/year)<br>03 March 1999 (03.03.99) | Priority date (day/month/year)<br>04 March 1998 (04.03.98) |
| Applicant<br>STAHL, Bronislaw-Jan                                      |  |

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:  
04 October 1999 (04.10.99)

☐ in a notice effecting later election filed with the International Bureau on:  
\_\_\_\_\_

2. The election ☒ was  
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

|   |                                   |
|---|-----------------------------------|
| The International Bureau of WIPO<br>34, chemin des Colombettes<br>1211 Geneva 20, Switzerland | Authorized officer<br>A. Karkachi |
| Facsimile No.: (41-22) 740.14.35  | Telephone No.: (41-22) 338.83.38  |

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

|  |   |  |
|--|---|--|
| Applicant's or agent's file reference<br><b>21274PC1</b> | <b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below. |  |
| International application No.<br><b>PCT/DK 99/ 00108</b> | International filing date (day/month/year)<br><b>03/03/1999</b>   | (Earliest) Priority Date (day/month/year)<br><b>04/03/1998</b> |
| Applicant<br><br><b>DANDY A/S et al.</b>                 |   |  |

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 2 sheets.  
☒ It is also accompanied by a copy of each prior art document cited in this report.

### 1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☒ None of the figures.

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

|    |                          |    |  |    |  |    |                          |
|----|--------------------------|----|--|----|--|----|--------------------------|
| AL | Albania                  | ES | Spain                                    | LS | Lesotho                                      | SI | Slovenia                 |
| AM | Armenia                  | FI | Finland                                  | LT | Lithuania                                    | SK | Slovakia                 |
| AT | Austria                  | FR | France                                   | LU | Luxembourg                                   | SN | Senegal                  |
| AU | Australia                | GA | Gabon                                    | LV | Latvia                                       | SZ | Swaziland                |
| AZ | Azerbaijan               | GB | United Kingdom                           | MC | Monaco                                       | TD | Chad                     |
| BA | Bosnia and Herzegovina   | GE | Georgia                                  | MD | Republic of Moldova                          | TG | Togo                     |
| BB | Barbados                 | GH | Ghana                                    | MG | Madagascar                                   | TJ | Tajikistan               |
| BE | Belgium                  | GN | Guinea                                   | MK | The former Yugoslav<br>Republic of Macedonia | TM | Turkmenistan             |
| BF | Burkina Faso             | GR | Greece                                   |    |  | TR | Turkey                   |
| BG | Bulgaria                 | HU | Hungary                                  | ML | Mali   | TT | Trinidad and Tobago      |
| BJ | Benin                    | IE | Ireland                                  | MN | Mongolia                                     | UA | Ukraine                  |
| BR | Brazil                   | IL | Israel                                   | MR | Mauritania                                   | UG | Uganda                   |
| BY | Belarus                  | IS | Iceland                                  | MW | Malawi                                       | US | United States of America |
| CA | Canada                   | IT | Italy                                    | MX | Mexico                                       | UZ | Uzbekistan               |
| CF | Central African Republic | JP | Japan                                    | NE | Niger  | VN | Viet Nam                 |
| CG | Congo                    | KE | Kenya                                    | NL | Netherlands                                  | YU | Yugoslavia               |
| CH | Switzerland              | KG | Kyrgyzstan                               | NO | Norway                                       | ZW | Zimbabwe                 |
| CI | Côte d'Ivoire            | KP | Democratic People's<br>Republic of Korea | NZ | New Zealand                                  |    |                          |
| CM | Cameroon                 |    |  | PL | Poland                                       |    |                          |
| CN | China                    | KR | Republic of Korea                        | PT | Portugal                                     |    |                          |
| CU | Cuba                     | KZ | Kazakhstan                               | RO | Romania                                      |    |                          |
| CZ | Czech Republic           | LC | Saint Lucia                              | RU | Russian Federation                           |    |                          |
| DE | Germany                  | LI | Liechtenstein                            | SD | Sudan  |    |                          |
| DK | Denmark                  | LK | Sri Lanka                                | SE | Sweden                                       |    |                          |
| EE | Estonia                  | LR | Liberia                                  | SG | Singapore                                    |    |                          |

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/DK 99/00108

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 A23G3/30

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A23G

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category * | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No.             |
|------------|---|-----------------------------------|
| X          | EP 0 263 224 A (WARNER-LAMBERT COMPANY)<br>13 April 1988<br>see claims; examples<br>---   | 1, 2, 19,<br>21, 24-32            |
| X          | US 4 250 195 A (CHERUKURI ET AL.)<br>10 February 1981<br><br>see line 1 - line 30<br>see column 6, line 33-36; examples<br>---    | 1-9,<br>11-13,<br>15-17,<br>25-32 |
| X          | EP 0 435 698 A (WM WRIGLEY JR. COMPANY)<br>3 July 1991<br>see page 1, line 13 - line 22<br>see page 2, line 25 - line 27<br>----- | 1-3, 16,<br>20, 22-24             |

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

3 June 1999

Date of mailing of the international search report

14/06/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Lepretre, F

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/DK 99/00108

| Patent document<br>cited in search report |   | Publication<br>date | Patent family<br>member(s) | Publication<br>date |
|---|---|---------------------|----------------------------|---------------------|
| EP 263224                                 | A | 13-04-1988          | US 4867989 A               | 19-09-1989          |
|   |   |                     | AU 6609286 A               | 17-03-1988          |
|   |   |                     | CA 1316747 A               | 27-04-1993          |
|   |   |                     | DE 3684920 A               | 21-05-1992          |
|   |   |                     | JP 1049455 B               | 24-10-1989          |
|   |   |                     | JP 1565623 C               | 25-06-1990          |
|   |   |                     | JP 63071151 A              | 31-03-1988          |
|   |   |                     | PT 83936 A,B               | 01-01-1987          |
|   |   |                     | ZA 8701912 A               | 31-08-1987          |
|   |   |                     |                            |                     |
| US 4250195                                | A | 10-02-1981          | AR 223394 A                | 14-08-1981          |
|   |   |                     | ZA 8005472 A               | 30-09-1981          |
| EP 435698                                 | A | 03-07-1991          | US 4988518 A               | 29-01-1991          |
|   |   |                     | AU 642453 B                | 21-10-1993          |
|   |   |                     | AU 6854390 A               | 11-07-1991          |
|   |   |                     | CA 2032829 C               | 08-08-1995          |
|   |   |                     | CN 1052995 A               | 17-07-1991          |
|   |   |                     | FI 906415 A                | 29-06-1991          |
|   |   |                     | PH 27260 A                 | 04-05-1993          |

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau

## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :

A23G 3/30

A1

(11) International Publication Number:

WO 99/44436

(43) International Publication Date: 10 September 1999 (10.09.99)

(21) International Application Number:

PCT/DK99/00108

(22) International Filing Date:

3 March 1999 (03.03.99)

(30) Priority Data:

0296/98

4 March 1998 (04.03.98)

DK

(71) Applicant (for all designated States except US): DANDY A/S  
[DK/DK]; Dandyvej 19, P.O. Box 208, DK-7100 Vejle  
(DK).

(72) Inventor; and

(75) Inventor/Applicant (for US only): STAHL, Bronislaw-Jan  
[DK/DK]; Magnoliavej 15, DK-7100 Vejle (DK).(74) Agent: PLOUGMANN, VINGTOFT & PARTNERS A/S;  
Sankt Annæ Plads 11, P.O. Box 3007, DK-1021 Copen-  
hagen K (DK).

(81) Designated States: AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published

With international search report.

(54) Title: A COATED CHEWING GUM, A METHOD FOR PREPARATION THEREOF AND THE USE OF ONE OR MORE ACTIVE SUBSTANCE(S) IN SOLID FORM

(57) Abstract

A coated chewing gum comprising a core of chewing gum and a coating comprising a coating material and one or more active substance(s) in solid form. The use of an active substance in solid form in the coating of a coated chewing gum provides a fast onset of the effect, a better stability of the active substance, and an increased effect thereof in all chewing phases.

## INTERNATIONAL SEARCH REPORT

Internatio application No

PCT/DK 99/00108

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A23G3/30

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A23G

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No.             |
|------------|---|-----------------------------------|
| X          | EP 0 263 224 A (WARNER-LAMBERT COMPANY)<br>13 April 1988<br>see claims; examples<br>---   | 1,2,19,<br>21,24-32               |
| X          | US 4 250 195 A (CHERUKURI ET AL.)<br>10 February 1981<br><br>see line 1 - line 30<br>see column 6, line 33-36; examples<br>---    | 1-9,<br>11-13,<br>15-17,<br>25-32 |
| X          | EP 0 435 698 A (WM WRIGLEY JR. COMPANY)<br>3 July 1991<br>see page 1, line 13 - line 22<br>see page 2, line 25 - line 27<br>----- | 1-3,16,<br>20,22-24               |

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"Z" document member of the same patent family

Date of the actual completion of the international search

3 June 1999

Date of mailing of the international search report

14/06/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Lepretre, F

09/623425

534 Rec'd PCT/PTC 0 5 SEP 2000

**COURTESY COPY OF THE**

**INTERNATIONAL PRELIMINARY**

**EXAMINATION REPORT WITH ANNEXES**

**CONTAINING NEW CLAIMS 1-30 TO**

**BE SUBSTITUTED FOR THE ORIGINAL**

**CLAIMS FOR EXAMINATION IN**

**THIS CASE**



## PATENT COOPERATION TREATY

PLOUGMANN  
VINGTOFT  
& PARTNERS

26 JUNI 2000

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

PLOUGMANN, VINGTOFT & PARTNERS A/S  
Sankt Annæ Plads 11  
P.O. Box 3007  
DK-1021 Copenhagen K  
DANEMARKPCT AM/AMNOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT  
(PCT Rule 71.1)Date of mailing  
(day/month/year) 23.06.2000Applicant's or agent's file reference  
21274 PC 1

## IMPORTANT NOTIFICATION

International application No.  
PCT/DK99/00108International filing date (day/month/year)  
03/03/1999Priority date (day/month/year)  
04/03/1998Applicant  
DANDY A/S et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

## 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/

European Patent Office  
D-80298 Munich  
Tel. +49 89 2399 - 0 Tx: 523656 epmu d  
Fax: +49 89 2399 - 4465

Authorized officer

Bleeker, M

Tel. +49 89 2399-8141



## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

|  |   |  |
|--|---|--|
| Applicant's or agent's file reference<br>21274 PC 1                                      | <b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |  |
| International application No.<br>PCT/DK99/00108  | International filing date (day/month/year)<br>03/03/1999  | Priority date (day/month/year)<br>04/03/1998 |
| International Patent Classification (IPC) or national classification and IPC<br>A23G3/30 |   |  |
| Applicant<br>DANDY A/S et al.  |   |  |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 5 sheets, including this cover sheet.

- ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

|  |   |
|--|---|
| Date of submission of the demand<br>04/10/1999   | Date of completion of this report<br>23.06.2000   |
| Name and mailing address of the international preliminary examining authority:<br><br>European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0 Tx: 523656 epmu d<br>Fax: +49 89 2399 - 4465 | Authorized officer<br><br>Paloniemi Legland, R<br><br>Telephone No. +49 89 2399 7315<br> |

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/DK99/00108

**I. Basis of the report**

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

**Description, pages:**

1-39 as originally filed

**Claims, No.:**

8-30 as received on 25/03/2000 with letter of 23/03/2000

1-7 with telefax of 08/06/2000

**Drawings, sheets:**

1/14-14/14 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☒ the claims, Nos.: 31  
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/DK99/00108

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

|                               |      |                |
|-------------------------------|------|----------------|
| Novelty (N)                   | Yes: | Claims 1-28,30 |
|                               | No:  | Claims 29      |
| Inventive step (IS)           | Yes: | Claims 1-27    |
|                               | No:  | Claims 28-30   |
| Industrial applicability (IA) | Yes: | Claims 1-30    |
|                               | No:  | Claims         |

**2. Citations and explanations****see separate sheet****VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

**see separate sheet****VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**INTERNATIONAL PRELIMINARY**

International application No. PCT/DK99/00108

**EXAMINATION REPORT - SEPARATE SHEET**

---

**Re Item I****Basis of the report**

The amendments fulfill the requirements of Art. 34(2)(b) PCT.

**Re Item V****Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents:

D1: EP-A-0 263 224 (WARNER-LAMBERT COMPANY) 13 April 1988

D2: US-A-4 250 195 (CHERUKURI ET AL.) 10 February 1981

D3: EP-A-0 435 698 (WM WRIGLEY JR. COMPANY) 3 July 1991

The amended claim 1 is directed to a coated chewing gum comprising a core of chewing gum and a coating comprising a coating material and one or more active substance(s), characterised in that the active substance(s) is/are added in **solid form** and is/are selected among **natural vegetable flavouring agents having a water content of less than 75 % by weight**, acids and high potent sweeteners.

Document D2, which is considered to represent the closest prior art, discloses a coated chewing gum (col.1, l.57-col.2, l.4). It differs from the application by having no water contents for the spray dried flavouring coating. The technical problem was to provide an alternative coated chewing gum with an increased stability of the active substance, a faster onset of the effect and a longer lasting explosion of taste. This problem was solved by a coated chewing gum consisting of active solid components as claimed in claim 1. This solution is not regarded as being obvious for the skilled person, because in the available prior art (D1 and D3) there are no hints to make a chewing gum with an active substance in solid form selected from natural vegetable flavouring agents with water content of less than 75 %, acids or high potent sweeteners. Thus the subject-matter of claims 1-22 is regarded to involve an inventive step (Art. 33(3) PCT).

The same reasoning applies to method claims 23-27.

The amended claim 29 is directed to a use of active substances selected among

**INTERNATIONAL PRELIMINARY**

International application No. PCT/DK99/00108

**EXAMINATION REPORT - SEPARATE SHEET**

---

natural flavour agents, acids, high potent sweeteners and functional substances in solid form in the coating to achieve a better stability of the active substance. D2 discloses a method for maintain the softness and freshness of the chewing gum piece even after prolonged storage (col. 1, l. 32-38). Therefore the subject-matter of claim 29 is not new. Features "fast onset of the effect" and "an increased effect of the active substance(s) in all chewing phases" in claims 28 and 30 are obvious effects of said coating and therefore do not involve an inventive step.

**Re Item VII****Certain defects in the international application**

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art is not indicated in the description and no corresponding documents (D1-D3) have been cited.

**Re Item VIII****Certain observations on the international application**

The term "approximately" used in amended claim 26 is vague and indefinite and as such render the scope of the claim unclear. In amended claim 17 the wording "any of the preceding claim(s)" should be in form "according to claim 16" and in amended claim 19 the word "is" is superfluous. In claim 23 under step 4) the wording "selected from claims 1-22" is missing. The vague and imprecise statement "Such variations are not...within the scope of the following claims." in the description on p. 39, l. 11-13 implies that the subject-matter for which the protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Art. 6 PCT).

18-06-2000

ECT/DK99/00108

Thursday 08 of Jun 2000, PV&amp;P 33639600

-&gt;+49 89 23994465

Page 2 of 4

Amended claims

8 June 2000

1. A coated chewing gum comprising a core of chewing gum and a coating comprising a coating material and one or more active substance(s), characterised in that the active substance(s) is/are added in solid form and is/are selected among natural vegetable flavouring agents having a water content of less than 75% by weight, acids, and high potent sweeteners.
2. The coated chewing gum according to claim 1 wherein the natural vegetable flavouring agent is selected among fruits and herbs.
3. The coated chewing gum according to claim 2 wherein the natural vegetable flavouring agent is selected among coconut, grape fruit, orange, lime, lemon, mandarin, pineapple, strawberry, raspberry, mango, passion fruit, kiwi, apple, pear, peach, apricot, cherry, grapes, banana, cranberry, blueberry, black currant, red currant, gooseberry, and lingonberry thyme, basil, valerian, fennel, parsley, camomile, tarragon, lavender, dill, cumin, bergamot, sage, aloe vera, spearmint, peppermint, eucalyptus, and mixtures thereof.
4. The coated chewing gum according to claim 3 wherein the water content of the natural vegetable flavouring agent is less than 60%, preferable less than 40%, more preferred less than 30%, such as less than 25%.
5. The coated chewing gum according to claim 4 wherein the water content of the natural vegetable flavouring agent is less than 20% by weight, such as less than 15%, more preferred less than 10% such as between 1.5-7%, more preferred between 2-6%.
6. The coated chewing gum according to any of claims 1-5 wherein the natural vegetable flavouring agent is freeze-dried.
7. The coated chewing gum according to any of claims 1-6 wherein the natural vegetable flavouring agent is in the form of a powder, slices or pieces or combinations thereof.

2

8. The coated chewing gum according to claim 7 wherein the natural vegetable flavouring agent is in a form where the particle size is less than 3mm, such as less than 2mm, more preferred less than 1mm, calculated as the longest dimension of the particle.
- 5 9. The coated chewing gum according to claim 7 wherein the natural vegetable flavouring agent is in a form where the particle size is from 3µm to 2mm, such as from 4µm to 1mm.
- 10 10. The coated chewing gum according to any of claims 1-9 wherein the natural vegetable flavouring agent comprises seeds from a fruit e.g. from strawberry, blackberry and raspberry, and which seeds are substantially intact.
11. The coated chewing gum according to any of the preceding claims wherein the natural vegetable flavouring agent also provides the gum formulation with natural colour.
- 15 12. The coated chewing gum according to claim 1, characterised in that the natural vegetable flavour is selected among peppermint, periwinkle, eucalyptus, spearmint, anethol, menthol, powdered anise, and fruit flavours such as orange, lemon, mango, pineapple, lime, strawberry, cherry, black currant, blueberry, 20 raspberry, wild berry, cranberry, apple, pear, banana, prune, and plum flavour.
13. The coated chewing gum according to claim 1, characterised in that the acids are selected among citric acid, malic acid, tartaric acid, lactic acid, and ascorbic acid.
- 25 14. The coated chewing gum according to claim 1, characterised in that the sweeteners are selected among aspartame, acesulfame K, saccharin, cyclamate, neohesperidine, thaumatin, glycyrrhizin, and salts thereof, monellin, sucralose, and alitame.
- 30 15. The coated chewing gum according to claim 1, characterised in that the functional substances are selected among vitamins, "cooling agents", flavour enhancers, and pharmaceuticals in the coating such as the vitamins A, B, C, D, and E, enzymes, nicotine, caffeine, acetylsalicylic acid, chlorhexidine, [zinc compounds], and antihistamines.

35

## AMENDED SHEET



Thursday 23 of Mar 2000, PV&P 33639600

3

16. The coated chewing gum according to any of the preceding claims wherein the active substance(s) is/are in an encapsulated form.
17. The coated chewing gum according to any of the preceding claim[s] 16  
5 wherein the encapsulated active substance is encapsulated in one or more material(s) selected among fatty substances, waxes, gelatine, gum arabic, starch, cellulose, cellulose derivatives, shellac, polyvinyl acetate, polyethylene, casein, zein, B cyclodextrine, silica, yeast cells, and a mixture of the above encapsulation materials, preferably a mixture of fatty substances and carnauba wax.
- 10 18. The coated chewing gum according to any of claims 1-17, characterised in that the coating additionally comprises one or more liquid active substance(s).
19. The coated chewing gum according to any of the preceding claims further  
15 comprising a flavour [is] selected among natural, naturally identical or synthetic flavours, and plant extracts.
20. The coated chewing gum according to claim 19, characterised in that the plant extracts are selected among extracts of liquorice, coffee, tea, herbs such as  
20 sage, thyme, basil, bergamot, balm, valerian, camomille, lavender, aloe vera, and spices such as pepper, cinnamon, capsicum, paprika, tarragon, fennel, mustard, dill, caraway, parsley, and tomato.
21. The coated chewing gum according to any of the preceeding claims further  
25 comprising a salt.
22. The coated chewing gum according to claim 21, characterised in that the salts are selected among sodium chloride, potassium chloride, ammonium chloride, sodium bicarbonate, and carbamide.
- 30 23. A method for the preparation of a coated chewing gum according to any of claims 1-22, characterised in that it comprises the following steps:
- 1) preparation of a core of chewing gum in a manner known per se.  
35 2) preparation of a coating suspension, also in a manner known per se,
- 3) application of the coating suspension onto the cores of chewing gum in a manner known per se,

AMENDED SHEET

4

4) Applying on the coating of one or more active substance(s) selected from 1-22 in solid form in one or more increment(s) after the application of the coating suspension, and optionally repeating step 3) and 4)

5

5) optionally, application of one or more liquid active substance(s) in one or more increment(s) between the applications of the coating suspension,

6) optionally, finally application of a surface layer.

10

24. The method according to claim 23, characterised in that the coating suspension comprises an aqueous solution of a sugar, a sugar alcohol, an artificial sweetener or mixtures thereof.

15 25. The method according to claim 24, characterised in that the coating suspension comprises an aqueous solution of one or more constituent(s) selected among saccharose, dextrose, sorbitol, xylitol, tagatose, mannitol, maltitol, isomalt, aspartame, acesulfame K, saccharine, cyclamate, taline, and neohesperidine.

20 26. The method according to any of claims 23-25, characterised in that the coating suspension is applied in approx. 2 to 90 increments, preferably in [approximately] 30-60 increments.

25 27. The method according to any of claims 23-26, characterised in that the active substance(s) present in solid form is/are applied in 1 to 10 increment(s) between the dosages of the coating suspension, preferably 1-4 increment(s).

30 28. The use of one or more active substance(s) selected among natural vegetable flavour agents, high potent sweeteners and functional substances in solid form in the coating of a coated chewing gum to achieve a fast onset of the effect.

35 29. The use of one or more active substance(s) selected among natural flavour agents, acids, high potent sweeteners, and functional substances in solid form in the coating of a coated chewing gum to achieve a better stability of the active substance.

30. The use of one or more active substance(s) selected among natural vegetable flavour agents, acids, high potent sweeteners, and functional substances in solid

AMENDED SHEET

Thursday 23 of Mar 2000, PV&P 33639600

5

form in the coating of a coated chewing gum to achieve an increased effect of the active substance(s) in all chewing phases.

AMENDED SHEET

PATENTBESKRIVELSE/21274PC1/AML/COU/23-03-00

Last printed 23/03/00 14:40

**COURTESY COPY OF THE  
PCT APPLICATION AS  
ORIGINALLY FILED WITH  
ABSTRACT**

WO 99/44436

14/PRTS

09/623425

PCT/DK99/00108

534 Rec'd PCT/PTO 05 SEP 2000

A Coated Chewing Gum, a Method for Preparation thereof and the Use of One or More Active Substance(s) in Solid Form

Technical Field

5

The present invention relates to a coated chewing gum comprising a core of chewing gum and a coating comprising a coating material as well as one or more active substance(s) in solid form. Furthermore, the invention relates to a method for the preparation of a coated chewing gum and the use of one or more active substance(s) in solid form in the coating of a coated chewing gum.

Technical Background

Coated chewing gum is prepared by coating a core of chewing gum with a number of layers of coating. The coating most often takes place in rotating coating kettles in which cores of chewing gum are rotated and coating suspension is applied in small portions that disperse evenly over the surfaces of the cores. Subsequently, the coated cores are dried by means of air.

These coating operations may be applied in up to approx. 90 increments until the preferred coating thickness is obtained, and the product has the preferred measures and the preferred weight.

The coating suspension is often an aqueous solution of a sugar or the like applied at an elevated temperature to ease the coating process.

In order to provide a fast flavour onset, often one or more flavour(s) is/are applied and possibly other active substances between the applications of the coating suspension. The active substance(s) is/are added in liquid form in one or more increment(s).

A chewing gum with a completed coating is normally finally treated with a surface layer of a wax or the like.

WO 99/44436

PCT/DK99/00108

2

The tablets with a completed coating are then subjected to a hardening process during the following approx. 8 weeks. Sugar alcohols such as sorbitol and xylitol thus form crystals whereby the chewing gum obtains a harder and a "crunchy" coating. The crystallisation process also provides a more porous coating structure. Thus, a migration  
5 of water, moisture and flavour takes place through the formed micro channels.

This causes the chewing gum to gradually lose its flavour, ethereal oils, if any, are oxidised, and the chewing gum loses moisture and gets harder.

10 Furthermore, the use of active substances in liquid form in the coating layers has the disadvantage that some of the active substances are lost to the surroundings during the coating process.

It has now been found that by using active substances in solid form in the coating  
15 layers of conventional chewing gum, an increased stability of the active substance is obtained. Furthermore, a faster onset of the effect is achieved, and by using flavour in solid form, a longer lasting explosion of taste compared with chewing gum coated with a liquid flavour. Finally, according to the invention, a more environmentally  
desirable manufacturing process is obtained since the use of an active substance in  
20 solid form causes less evaporation of volatile substances.

#### Disclosure of the Invention

Thus, the invention relates to a coated chewing gum comprising a core of chewing  
25 gum and a coating which comprises a coating material, and one or more active substance(s), which chewing gum is characterised in that the active substance(s) is/are added in solid form.

Furthermore, the invention relates to a method for the preparation of a coated  
30 chewing gum according to the invention, which method is characterised in that it comprises the following steps:

- 1) preparation of a core of chewing gum in a manner known *per se*,

WO 99/44436

PCT/DK99/00108

3

- 2) preparation of a coating suspension, also in a manner known *per se*,
- 3) repeated applications of the coating suspension onto the cores of chewing gum also in a manner known *per se*, preferable at a temperature in the interval 30-90°C, preferably 35-75°C,

5

- 4) Applying on the coating of one or more active substance(s) in solid form in one or more increment(s) after the application of the coating suspension, and optionally repeating step 3) and 4)

10

- 5) optionally, application of one or more liquid active substance(s) in one or more increment(s) between the applications of the coating suspension,

- 6) optionally, finally application of a surface layer.

15

Applying of the solid active substance(s) is/are preferable performed without drying of the coating suspension in order to enable adherence of a substantial amount of the substance(s) in solid form to the coating. The drying time for the coating suspension depends on the specific coating formulation, however, the active substance(s) is/are added to the coated chewing gum substantially without delay after the coating processes are finished. If desired, the coated chewing gum may be wetted before adding the active substance(s) in solid form in case the coating has been allowed to dry for too long time whereby the coated chewing gum is no longer sticky.

20

25 The coating process may be repeated as many times as needed in order to obtain the desired thickness of the coating. In the coating process, the active substance(s) in solid form may be added between one or more of the ordinary coating processes. The last layer of the coating process may also include the active substance(s) in solid form. It is also within the present invention to use different active substances in solid form in the same coating layer or use one active substance in one layer, and a second active substance in another layer. Such combinations of active substances may be flavour and high potent sweeteners or a medicament together with an substance decreasing an undesirable taste of the medicament.

30

WO 99/44436

PCT/DK99/00108

4

As the active substance(s) is/are located in the outer part of the coating, the active substance(s) is/are exposed to the consumer within a short period of chewing.

Accordingly, in a further embodiment, the invention relates to the use of one or more active substance(s) in solid form in the coating of a coated chewing gum in order to  
5 obtain a fast onset of the effect.

A further advantage of the admixture of the active substance(s) in solid form is that the solid form is more resistant to decomposition. Accordingly, the invention also relates to the use of one or more active substance(s) in solid form in the coating of a  
10 coated chewing gum in order to obtain a better stability of the active substance(s).

Finally, the invention relates to the use of one or more active substance(s) in solid form in the coating of a coated chewing gum in order to obtain an increased effect of the active substance(s) in all chewing phases.

15

#### Brief Description of the Drawing

The invention is further illustrated by means of the drawing, in which

20 Fig. 1 shows the release of flavour as a function of time by using menthol/-anethol/eucalyptus flavour in encapsulated form and liquid form, respectively,

Fig. 2 shows the release of flavour as a function of time by using the same amount of eucalyptus/anethol/menthol flavour in encapsulated form and liquid form, respectively,

25 Fig. 3 shows the release of flavour as a function of time by using liquid eucalyptus/anethol/menthol flavour and with and without encapsulated menthol,

Fig. 4 shows the stability of chewing gum with apple/cinnamon flavour with encapsulated and non-encapsulated aspartame, respectively, in suspension form in the  
30 coating,

Fig. 5 shows a flavour profile in the initial phase of chewing gum with fruit flavour (lemon/orange/mango) with and without encapsulated citric acid in the coating,



WO 99/44436

PCT/DK99/00108

5

Fig. 6 shows a flavour profile in the initial phase of a chewing gum with fruit flavour (lemon/orange/mango) with and without encapsulated "cooling agent" in the coating,

Fig. 7 shows the same in the intermediate phase,

5

Fig. 8 shows the same in the end phase,

Fig. 9 shows a flavour profile in the initial phase of chewing gum with menthol/-anethol/eucalyptus flavour and with encapsulated thyme extract in the coating,

10

Fig. 10 shows the same in the intermediate phase,

Fig. 11 shows the same in the end phase,

15 Fig. 12 shows a flavour profile in the initial phase of chewing gum with menthol/-anethol/eucalyptus flavour and with encapsulated extract of black pepper in the coating,

Fig. 13 shows the same in the intermediate phase, and

20

Fig. 14 shows the same in the end phase.

The scope of the invention will appear from the detailed description below. However, it should be understood that the detailed description and the specific examples, while  
25 indicating preferred embodiments of the invention, are given by way of illustration only, since various changes and modifications within the scope of the invention will become apparent for those skilled in the art from the detailed description.

#### Detailed Description of the Invention

30

The active substances are selected among flavours, acids, salts, high potent sweeteners, and functional substances.

WO 99/44436

PCT/DK99/00108

6

Aromas, which may be incorporated into the chewing gum according to the invention, are selected among natural, naturally identical or synthetic flavours, as well as plant extracts. Examples of applicable flavours are for example peppermint, periwinkle, eucalyptus, spearmint, anethol, menthof, powdered anise, and fruit flavours such as  
 5 orange, lemon, mango, pineapple, lime, strawberry, cherry, black currant, blueberry, raspberry, wild berry, cranberry, apple, pear, banana, prune, and plum flavour, etc.

The plant extracts which may be applied instead of or together with one or more of the above-mentioned flavour(s) are preferably selected among extracts of liquorice,  
 10 coffee, tea, herbs such as sage, thyme, basil, bergamot, balm, valerian, camomile, lavender, aloe vera, and spices such as pepper, cinnamon, capsicum, paprika, tarragon, fennel, mustard, dill, caraway, parsley, tomato, etc.

The use of plant extracts in coated chewing gum provides the possibility of preparing  
 15 novel combinations of flavour and new flavour experiences.

In a preferred embodiment of the invention the active substance(s) is/are a natural vegetable flavouring agent such as fruit and herbs. Accordingly the substance may be selected among coconut, grape fruit, orange, lime, lemon, mandarin, pineapple,  
 20 strawberry, raspberry, mango, passion fruit, kiwi, apple, pear, peach, apricot, cherry, pineapple, grapes, banana, cranberry, blueberry, black currant, red currant, gooseberry, and lingonberry, thyme, basil, valerian, fennel, parsley, camomile, tarragon, lavender, dill, cumin, bergamot, sage, aloe vera, spearmint, peppermint, eucalyptus and mixtures thereof.

25

It is furthermore an advantage that the natural flavouring agent is dried. A dried agent may have a more intense flavour and may further increase the stability of the flavour because many of the notes of the taste are still present in the more or less intact cells of the fruit or herb. The limited content of water is also an important factor with  
 30 respect to stability.

In a further aspect, the water content of the natural flavouring agent is less than 75% by weight, such as less than 60%, preferable less than 40%, more preferred less than 30%, such as less than 25%. However, in situations where a less water content is

WO 99/44436

PCT/DK99/00108

7

desired (for stability reasons or with respect to have an increased flavour sensation), the water content of the natural flavouring agent is less than 20% by weight, such as less than 15%, more preferred less than 10% such as between 1.5-7%, more preferred between 2-6%.

5

In a preferred embodiment, the natural flavouring agent is freeze-dried.

The natural flavouring agent in solid form may be in the form of a powder, slices or pieces, or combinations thereof. When a natural vegetable flavour is used, it is generally accepted or even desired that a feeling of small pieces of the flavour agent be recognised by the consumer in the chewing process. Accordingly, the natural flavouring agent may be in a form where the particle size is up to 3mm or even more. However smaller pieces are preferred and in a further aspect, the particle size is less than 3mm, such as less than 2mm, more preferred less than 1mm, calculated as the longest dimension of the particle.

In other situations it may be an advantage to have different sizes of the particles and an example is wherein the natural flavouring agent is in a form where the particle size is from about 3 $\mu$  to 2mm, such as from 4 $\mu$  to 1mm. However, the skilled person may select any combination dependent on the desired final properties of the coated chewing gum.

As seeds from fruits may have a special flavour, the natural flavouring agent may comprise seeds from a fruit e.g. from strawberry, blackberry and raspberry, and which seeds are substantially intact.

In a still further aspect of the invention, the natural vegetable flavouring agent also provides the gum formulation with natural colour. With seeds of a vegetable or fruit flavouring agents such as strawberry and/or orange, it has been possible to obtain a marbling colouring of the chewing gum as well as a uniform colouring. Accordingly, in a further aspect of the invention, the active substance in solid form may be a colouring agent.

WO 99/44436

PCT/DK99/00108

8

Various acids may also be applied as active substances, such as citric acid, malic acid, tartaric acid, lactic acid, and ascorbic acid or any other acid allowed in food and which is suitable. These may most conveniently be applied together with chewing gum with fruit flavour in order to obtain an improved freshness during the first phase of the  
5 chewing period.

Furthermore, according to the invention, instead of or together with one or more of the above-mentioned active substance(s), salts may be applied, such as sodium chloride, potassium chloride, ammonium chloride, sodium bicarbonate, and carbamide.  
10 Hereby an improved chewing gum taste during the initial chewing period is obtained, and in case of sodium bicarbonate and carbamide also an improved dental care effect.

In order to obtain a sweet taste during the initial chewing period, together with or instead of one or more of the above-mentioned active substance(s) sweeteners may  
15 be incorporated in the coating, preferably highly potent sweeteners. Especially suitable sweeteners are e.g. aspartame, acesulfame K, saccharin, cyclamate, neohesperidine, thaumatin, glycyrrhizin, and salts thereof, monellin, sucralose, and alitame.

Finally, in order to obtain a specific effect together with or instead of one or more of  
20 the above-mentioned active substance(s), one or more functional substance(s) can be incorporated in the coating such as vitamins and nutrients, "cooling agents", flavour enhancers, enzymes, agents for care and treatment of the oral cavity, antiseptic agents, pharmaceuticals and herbal medicine.

25 "Cooling agents" and flavour enhancers are substances manufactured by so-called "flavour houses", and which substances are also known as "flavour enhancer", "cooling flavour", "physcol", "optacool", and the like. They are applied in order to make the taste stronger and fresh.

30 Examples of cooling agents are e.g. lactic acid menthyl ester, disclosed in EP 0794169 A1, mono menthylsuccinate, and salts thereof, disclosed in WO97/07771, and 4-(1-menthoxymenthyl)-2-phenyl-1,3-dioxolan and derivatives thereof, disclosed in US 5,545,424.

WO 99/44436

PCT/DK99/00108

9

Among the vitamins and the nutrients that may be incorporated in the chewing gum according to the invention special mention can be made, without limitation, of the vitamins A, B<sub>1</sub>, B<sub>2</sub>, B<sub>5</sub>, B<sub>6</sub>, B<sub>12</sub>, D<sub>3</sub>, E, K, folic acid, niacin, biotin,  $\beta$ -carotene, ascorbic acid, and salts thereof, amino acids, glycerophosphates, minerals in the form of salts, 5 complexes and compounds containing calcium, phosphorus, magnesium, iron, zinc, copper, iodine, manganese, chromium, selenium, molybdenum, potassium, sodium, or cobalt and ubiquinon.

Among agents for the care and treatment of the oral cavity, special mention may be 10 made of hydrogen peroxide, carbamide and carbamide releasing compounds, CPP (caseinphosphopeptide), fluorine compounds such as sodium fluoride, sodium monofluorophosphate, and stannofluoride, arginine, zinc compounds, strontium chloride and potassium nitrate.

15 Among antiseptic agents, special mention may be made of guanidine and biguanidine, such as chlorhexidine acetate, quaternary ammonium compounds such as benzalkonium chloride, cetylpyridinium chloride, and cetrimide, phenols such as tymol, triclosan, parachlorophenol, and cresol, hexachlorophen as well as salicylanilide compounds.

20

Enzymes may also be incorporated in the chewing gum according to the invention, e.g. papain, trypsin, amylglucosidase, lactase, glucoseoxidase, streptokinase, streptodornase, dextranase, and mutanase.

25 Among pharmaceuticals, special mention may be made of caffeine, salicylic acid, and derivatives thereof, such as acetylsalicylic acid, choline salicylate, and magnesium salicylate, paracetamol, salts of pentazocine, buprenorphine, and buprenorphine hydrochloride, codeine hydrochloride and phosphate, morphine and salts thereof, methadone hydrochloride, ketobemidone,  $\beta$  blockers, calcium antagonists, verapamil 30 hydrochloride, verapamil, nifedipine, nitroglycerin, erythryl tetranitrate, strychnine and salts thereof, lidocaine, tetracaine hydrochloride, etorphine hydrochloride, atropine, insulin, alfa-amylase, polypeptides such as oxytocin, gonadorelin, and LHRH, desmopressin acetate (DDAVP), isoxsuprine hydrochloride, ergotamine compounds, chloroquine phosphate and sulfate, isosorbide, demoxytocin, heparin, lupeol,

WO 99/44436

PCT/DK99/00108

10

sucralfate and salts thereof, nicotine and salts and derivatives thereof, lobeline, cinnarizine, dimenhydrinate, difenhydramine, cyclizine, scopolamine, miconazole, nystatin, metronidazole, hydrocortisone, astemizole, benzocaine, glibenglamide, onsaedantrinum, acyclovir, sumatriptan, tropisetron, pizotifen, cisapride,  
5 domperidone, itraconazole, omeprazole, terfenadine, fluconazole, naratriptan, zolmriptan, rizatriptan, eletriptan, almotriptan, sildenafil, tolfenamic acid, tramadol, cetirzine, and loratidine.

Among herbal medicine special mention may be of ginkgo biloba, ginseng, saw  
10 palmetto, stevia, ginger, propolis, echinacea, St. John's Wort, Siberian ginseng, guarana, and garlic in the form of drugs, extracts or in purified form.

Furthermore, it is possible by means of the present invention to add substances, which cannot resist the thermal and mechanical influences that normally occur during  
15 the manufacturing of cores of chewing gum, such substances being certain vitamins, enzymes, and pharmaceuticals.

The active substance(s) is/are added in the form of dry active substance, preferably spray-dried active substance, or in the form of encapsulated active substance. In a  
20 preferred embodiment of the present invention, the active substance is present in an encapsulated form. The active substance is preferably present in the form of a powder with particles having a size of 3-300  $\mu\text{m}$ .

The use of encapsulated active substance provides a larger stability of the substance,  
25 and the active substance migrates very slowly to the surface of the coated chewing gum. Furthermore, the contact of the encapsulated active substances with the air is limited, whereby possible oxidation processes take place very slowly. The latter are of particular significance in connection with flavours, especially in the form of ethereal oils, such as peppermint, lemon, lime, and orange.

30

In addition, by encapsulating the active substance, it is achieved that its reaction with other substances is prevented, substances like e.g. sodium bicarbonate with acid and aspartame with aldehyde-containing flavours, and especially in case of substances with an unpleasant taste, e.g. certain pharmaceuticals, the taste may be camouflaged.

WO 99/44436

PCT/DK99/00108

11

In addition, it has been found that by chewing chewing gum that is coated with encapsulated flavour, not only a strong taste explosion is achieved, but also an enhanced taste in all chewing phases. The latter is due to the fact that flavour capsules from the coating layer of the chewing gum are opened both during the initial chewing and in following chewing period.

Furthermore, using an encapsulated active substance may prevent a discoloration of the coating, e.g. plant extracts such as thyme or black pepper. Finally, it may be desirable to prevent water-solubility, e.g. in connection with the use of acids and salts as the active substance.

When an encapsulated active substance is used, conventionally used encapsulation agents are used as the encapsulation agent, for instance, but without limitation, fatty substances, waxes, gelatin, gum arabic, starch, cellulose, cellulose derivatives, shellac, polyvinyl acetate (PVA), polyethylene (PE), casein, zein, B cyclodextrine, silica, yeast cells, and a mixture of the above encapsulation agents. Preferred encapsulation agents comprise fatty substances such as hydrogenated soy bean, cottonseed, coconut, sunflower, palm kernel, rapeseed, and ricinus oil, or waxes such as bees' wax, candelilla wax, carnauba wax, paraffin wax, and polyethylene wax, etc. Especially preferred is the use of a mixture of hydrogenated rape oil and carnauba wax.

Encapsulated flavour and methods for encapsulation are known from, e.g., EP 0 170 752 A2, EP 0 453 397 A1, EP 0 455 598 B1, and US 4,386,106.

In a particularly preferred embodiment of the coated chewing gum according to the present invention, the coating also comprises besides the coating material as well as one or more active substance(s) in solid form, one or more liquid active substance(s). This provides a larger flexibility of the process of chewing gum manufacture, and, when encapsulated active substance is concerned, a reduction in costs, since the encapsulation makes the process more expensive, and it is thus reserved for only the most sensitive active substances.

WO 99/44436

PCT/DK99/00108

12

In one embodiment of the invention, the coating suspension comprises an aqueous solution of a sugar, a sugar alcohol, an artificial sweetener or mixtures thereof, preferably an aqueous solution of saccharose, dextrose, sorbitol, xylitol, tagatose, mannitol, maltitol, isomalt, aspartame, acesulfame K, saccharin, cyclamate, thalline, 5 and neohesperidine.

The coating suspension is applied in approx. 2 to 90 increment(s), preferably in approx. 30-60 increments to achieve a uniform coating with a suitable thickness.

- 10 The active substance(s) is/are applied by sprinkling or by blowing the substances into the rotating kettles a number of times such as from 1 to 10 times between the dosages of the coating suspension, preferably approx. 1 to 4 times to achieve a suitable effect.
- 15 The following is a general description of the preparation of chewing gum.

#### Preparation of Chewing Gum

The preparation process comprises the following:

20

Mixing of conventional chewing gum components in kneading kettles (mixers) with strong horizontally placed Z-shaped arms, which processes the raw materials and produces a homogeneous gum mass.

- 25 The kneading kettles are heated to a temperature of 30-80°C, typically approx. 45°C. The mixing process starts with gum base quantities that have been weighed out, and the processing of these lasts for 1-20 minutes, typically approx. 10 minutes. Then one or more sweetener(s) in powder form or in liquid form is/are added. The dosage of sweeteners and the following processing last from 1 to 20 minutes, typically approx. 30 7 minutes.

Then the flavours and the remaining components are added and kneaded for a further 1 to 10 minutes, typically approx. 5 minutes. The admixture of flavours and the remaining components may also take place in the beginning of the kneading process,



WO 99/44436

PCT/DK99/00108

13

i.e. before the admixture of the sweeteners. It is also possible to add flavours in two or more portions during the kneading process.

When the kneading is completed, the kneading kettle is tipped, and the gum mass is  
5 taken out into carts, onto trays or the like.

The next process is the forming of the chewing gum. Before the forming can take place, the chewing gum mass, however, must be cooled. When taken out, the chewing gum mass has a temperature of 50-70°C, and in order to form the chewing  
10 gum, the temperature must be reduced to 30-45°C. The cooling of the chewing gum either takes place by storing the chewing gum mass in carts or on trays for quite a long time or by transporting a thin chewing gum carpet through a cooling tunnel.

The forming of the chewing gum may take place by extrusion through a specially  
15 formed nozzle, or the chewing gum may be formed after extrusion by means of rollers, punching machines, tentering wheels, and the like.

The chewing gum may be formed into cores, sticks, balls, cubes, cylinders, and many other shapes.

20

In order to prevent the chewing gum from sticking to the rollers and other tools, the chewing gum is frequently powdered with a powder, which may consist of i.a. icing sugar, talc, corn flour, and the like.

25 The formed chewing gum can be cooled immediately to room temperature in a cooling tunnel and be packed (especially in case of bubble gum and soft bubble gum), or the cooling may take place on trays at the store for semimanufactured products at a controlled temperature and moisture.

30 The formed and cooled chewing gum is then treated by means coating and polishing processes before the packing.

WO 99/44436

PCT/DK99/00108

14

Coating and Polishing of Cores of Chewing Gum

The coating of cores takes place in tilted, round or horizontally placed cylindrical coating kettles that rotate during the whole process. The coating kettles are made  
5 from copper, stainless steel or fiberglass-reinforced polyester, and are often equipped with a piping system that supplies and exhausts air and doses the coating suspension.

The coating process may take place as follows:

Cores of chewing put into movement in rotating coating kettles are added to the  
10 coating suspension in small portions that disperse evenly over the surfaces of the cores after a short or long smoothing out time. (The smoothing out time is the period of time during which the suspension disperses over the cores, approx. 10-90 seconds, preferably approx. 30-60 seconds). Afterwards the cores are dried by means of air. The operation is repeated up to 90 times, preferably approx. 30-40 times, until the  
15 cores are completely covered and have the preferred measure and the preferred weight.

In order to ease the coating process of chewing gum, a suspension is used which is heated up to 90°C, preferable up to about 75°C, and air which is heated up to at least  
20 35°C such as about 40°C.

Between the dosages of the coating suspension, one or more active substance(s) in solid form is/are added in one or more increment(s) in order to provide the chewing gum with a fast effect, e.g. flavour release during the chewing. It is an important  
25 aspect of the invention that the drying period is extended to after applying the active substances. When the active substances are added just after the coating process is completed, the coating suspension is still soft and the active substances may be more or less embedded in the coating in the solid form. The skilled person will be able to estimate or to establish by a simple test when the active substance should be added  
30 for obtaining a sufficient adherence of the active ingredient to the coating.

As appears from the Examples, the drying period is 0 seconds, however, drying periods up to 50 seconds such as up to 25 seconds are within the present invention and even longer periods may be acceptable depending on the drying properties of the

WO 99/44436

PCT/DK99/00108

15

coating suspension, the particle size of the active substance as well as whether it is desired that the active substance should be fully embedded in the coating or should form a superficial layer on the coating.

- 5 Furthermore, between the dosages of the coating suspension and the addition of one or more active substance(s) in solid form, one or more active substance(s) in liquid form may be added.

- 10 In order to achieve a neat and smooth surface of the chewing gum tablets with the completed coating, these may subsequently be subjected to a polishing. The polishing also takes place in rotating coating kettles in which a polishing suspension or a polishing powder is added to the coated cores in one or more portion(s). The polishing suspension often consists of wax, emulsifier, shellac, gum arabic, water, etc. The polishing powder often consists of wax only, or of wax mixed with emulsifier, gum  
15 arabic or talc, etc.

The present invention is further illustrated below by means of some examples.

WO 99/44436

PCT/DK99/00108

16

Examples

As a starting point, partly sugar-containing, partly sugar-free cores of chewing gum  
5 are used which are rolled out into sheets by means of stamping rollers, i.e. coherent sheets of cores of chewing gum which have a weight of approx. 0.9g/piece.

A coating kettle DRIA 1200, supplied by Driam Metallprodukt GmbH, Germany, is used for the coating of the above-mentioned cores. DRIA 1200 is a horizontally placed  
10 and cylindrical kettle intended for the coating of 50kg of chewing gum cores. The equipment has computer controlling of the amount of dosages of liquid and solid substances as well as controlling of the smoothing out times, the drying times, air quantities, the temperature of the drying air, and the airflow direction. For dosage of an active substance in a solid form, a pneumatic conveyor having a dispersing arm  
15 which ensures an even dispersion of the powder over all the tablets. The coating kettle can be set at various velocities from 1 to 15 rpm.

During the coating process, 50kg of chewing gum cores are filled into the coating kettle that can be set to a rotation of 8 rpm. During this rotation, the cores of chewing  
20 gum are separated from each other. Drying air is applied to the equipment, and surplus talc, which has been added during the rolling out of the cores of chewing gum, is removed. This separation and blowing through of air last for approx. 5 minutes.

Then the rotation speed of the coating kettle is increased to 11 rpm, and the first  
25 dosage of the coating suspension may take place.

It is also possible to use small (2kg) or large (100kg) tilted, round coating kettles and sprinkle active substance in solid form manually in 1-10 increment(s) between the dosages of the coating suspension. Dosage of active substance in more increments  
30 ensures an even dispersion of the powder over all the cores of chewing gum.

For the coating of sugar-containing cores of chewing gum, a saccharose suspension was used in the following examples, and a sorbitol suspension was used for the coating of sugar-free cores.

WO 99/44436

PCT/DK99/00108

17

In the following embodiments, the coating suspension had the following composition:

1. Saccharose suspension

5

|                                |         |
|--------------------------------|---------|
| Sugar juice (70%)              | 94.45 % |
| Water                          | 4.68 %  |
| Gelatine (Bloom value 120-160) | 0.87 %  |

10

-----  
Total 100.00 %

2. Sorbitol suspension

15

|                               |         |
|-------------------------------|---------|
| Sorbitol liquid/neosorb 70/02 | 97.86 % |
| Water                         | 1.59 %  |
| Titanium dioxide              | 0.55 %  |

-----  
Total 100.00 %

20 The Examples 1, 2, and 3, shows conventional coating of sugar-containing and sugar-free cores of chewing gum, respectively.

WO 99/44436

PCT/DK99/00108

18

## Example 1

Coating in DRIA 1200 equipment of 50kg of sugar-containing chewing gum cores with peppermint taste.

5

| Saccharose suspension | Amount of dosage<br>g | Smoothing out<br>time<br>sec. | Drying time<br>sec. | Drum<br>rpm |
|-----------------------|-----------------------|-------------------------------|---------------------|-------------|
| Dosage No.            |                       |                               |                     |             |
| 1-2                   | 500                   | 45                            | 300                 | 11          |
| 3-12                  | 900                   | 45                            | 400                 | 11          |
| 13                    | 600 + 222*            | 60                            | 400                 | 11          |
| 14-15                 | 700                   | 0                             | 380                 | 11          |
| 16-21                 | 1000                  | 0                             | 380                 | 11          |
| 22-34                 | 1000                  | 30                            | 410                 | 11          |
| 35-38                 | 600                   | 260                           | 280                 | 11          |
| 39                    | 500                   | 1500                          | 290                 | 11          |
| 40                    | wax powder 50g        | 300                           | 300                 | 8           |

\* A 600g saccharose suspension + 222g peppermint oil.

WO 99/44436

PCT/DK99/00108

19

## Example 2

Coating in DRIA 1200 equipment of 50kg of sugar-free chewing gum cores with peppermint taste.

5

| Sorbitol<br>suspension | Amount of dosage<br>g | Smoothing out<br>time<br>sec. | Drying time<br>sec. | Drum<br>rpm |
|------------------------|-----------------------|-------------------------------|---------------------|-------------|
| Dosage No.             |                       |                               |                     |             |
| 1-2                    | 400                   | 0                             | 250                 | 11          |
| 3-5                    | 700                   | 15                            | 300                 | 11          |
| 6                      | 700 + 200*            | 60                            | 300                 | 11          |
| 7-16                   | 700                   | 45                            | 300                 | 11          |
| 17-24                  | 1000                  | 45                            | 350                 | 11          |
| 25-26                  | 700                   | 240                           | 240                 | 11          |
| 27                     | wax powder 50g        | 360                           | 360                 | 8           |

\* A 700g sorbitol suspension + 200g peppermint oil.

WO 99/44436

PCT/DK99/00108

20

## Example 3

Coating in tilted kettles of 2kg sugar-free chewing gum cores with a mixture of liquid eucalyptus, menthol, and anethol.

5

| Sorbitol<br>suspension<br>Dosage No. | Amount of dosage<br>g | Smoothing out<br>time<br>sec. | Drying<br>time<br>sec. | Number of<br>revolutions<br>rpm |
|--------------------------------------|-----------------------|-------------------------------|------------------------|---------------------------------|
| 1                                    | 20                    | 120                           | 120                    | 50                              |
| 2                                    | 20                    | 90                            | 120                    | 50                              |
| 3                                    | 20                    | 60                            | 60                     | 50                              |
| 4-9                                  | 30                    | 30                            | 90                     | 50                              |
| 10-11                                | 30                    | 30                            | 120                    | 50                              |
| 12                                   | 20*                   | 60                            | 120                    | 50                              |
| 13                                   | 9.9 liquid<br>flavour | 10                            | 0                      | 50                              |
| 14                                   | 20                    | 40                            | 0                      | 50                              |
| 15-16                                | 20                    | 5                             | 120                    | 50                              |
| 17-22                                | 30                    | 60                            | 120                    | 50                              |
| 23-26                                | 40                    | 30                            | 120                    | 50                              |
| 27-33                                | 30                    | 60                            | 120                    | 50                              |
| 34-35                                | 20                    | 120                           | 240                    | 50                              |
| 36                                   | wax powder 2g         | 300                           | 300                    | 50                              |

\* A sorbitol suspension with 3.5% aspartame and 7.5% acesulfame K.



WO 99/44436

PCT/DK99/00108

21

## Example 4

Coating in DRIA 1200 equipment of 50kg sugar-containing chewing gum cores with peppermint oil encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

| Saccharose<br>suspension<br>Dosage No. | Amount of dosage<br>g | Smoothing out<br>time<br>sec. | Drying time<br>sec. | Drum<br>rpm |
|--|-----------------------|-------------------------------|---------------------|-------------|
| 1-2                                    | 500                   | 45                            | 300                 | 11          |
| 3-12                                   | 900                   | 45                            | 400                 | 11          |
| 13                                     | 400                   | 10                            | 0                   | 11          |
| 14                                     | 400* powder           | 60                            | 0                   | 11          |
| 15-16                                  | 700                   | 0                             | 380                 | 11          |
| 17                                     | 400                   | 10                            | 0                   | 11          |
| 18                                     | 400* powder           | 60                            | 0                   | 11          |
| 19-20                                  | 700                   | 0                             | 380                 | 11          |
| 21-24                                  | 1000                  | 0                             | 380                 | 11          |
| 25-37                                  | 1000                  | 30                            | 410                 | 11          |
| 38-41                                  | 700                   | 260                           | 280                 | 11          |
| 42                                     | 500                   | 1500                          | 290                 | 11          |
| 43                                     | wax powder 50g        | 300                           | 300                 | 8           |

\* A powder with a flavour concentration of 28%.

WO 99/44436

PCT/DK99/00108

22

## Example 5

Coating in DRIA 1200 equipment of 50kg sugar-free chewing gum cores with peppermint oil encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

| Sorbitol<br>suspension<br>Dosage No. | Amount of dosage<br>g | Smoothing out<br>time<br>sec. | Drying time<br>sec. | Drum<br>rpm |
|--------------------------------------|-----------------------|-------------------------------|---------------------|-------------|
| 1-2                                  | 400                   | 0                             | 250                 | 11          |
| 3-5                                  | 700                   | 15                            | 300                 | 11          |
| 6                                    | 350                   | 10                            | 0                   | 11          |
| 7                                    | 360* powder           | 60                            | 0                   | 11          |
| 8-9                                  | 700                   | 10                            | 300                 | 11          |
| 10                                   | 350                   | 10                            | 0                   | 11          |
| 11                                   | 360* powder           | 60                            | 0                   | 11          |
| 12-13                                | 700                   | 10                            | 300                 | 11          |
| 14-18                                | 700                   | 45                            | 300                 | 11          |
| 19-26                                | 1000                  | 45                            | 350                 | 11          |
| 27-28                                | 700                   | 240                           | 240                 | 11          |
| 29                                   | wax powder 50g        | 360                           | 360                 | 8           |

\* A powder with a flavour concentration of 28%.

WO 99/44436

PCT/DK99/00108

23

## Example 6

Coating in tilted round kettles of 2kg sugar-free chewing gum cores with peppermint oil encapsulated in silica.

5

| Sorbitol<br>suspension<br>Dosage No. | Amount of dosage<br>g | Smoothing out<br>time<br>sec. | Drying time<br>sec. | Number of<br>revolutions<br>rpm |
|--------------------------------------|-----------------------|-------------------------------|---------------------|---------------------------------|
| 1                                    | 20                    | 120                           | 120                 | 50                              |
| 2                                    | 20                    | 90                            | 120                 | 50                              |
| 3                                    | 20                    | 60                            | 60                  | 50                              |
| 4-9                                  | 30                    | 30                            | 90                  | 50                              |
| 10-11                                | 30                    | 30                            | 120                 | 50                              |
| 12                                   | 20*                   | 60                            | 120                 | 50                              |
| 13                                   | 20                    | 10                            | 0                   | 50                              |
| 14                                   | 17** powder           | 40                            | 0                   | 50                              |
| 15-16                                | 20                    | 5                             | 120                 | 50                              |
| 17-19                                | 30                    | 60                            | 120                 | 50                              |
| 20-28                                | 40                    | 30                            | 120                 | 50                              |
| 29-33                                | 30                    | 60                            | 120                 | 50                              |
| 34-35                                | 20                    | 120                           | 240                 | 50                              |
| 36                                   | wax powder 2g         | 300                           | 300                 | 50                              |

\* A sorbitol suspension with 2.75% aspartame.

\*\* A powder with a flavour concentration of 50%.

WO 99/44436

PCT/DK99/00108

24

**Example 7**

Coating in tilted kettles of 2kg sugar-free chewing gum cores with peppermint oil encapsulated in gelatine.

5

| Sorbitol<br>suspension<br>Dosage No. | Amount of<br>dosage<br>g | Smoothing out<br>time<br>sec. | Drying time<br>sec. | Number of<br>revolutions<br>rpm |
|--------------------------------------|--------------------------|-------------------------------|---------------------|---------------------------------|
| 1                                    | 20                       | 120                           | 120                 | 50                              |
| 2                                    | 20                       | 90                            | 120                 | 50                              |
| 3                                    | 20                       | 60                            | 60                  | 50                              |
| 4-9                                  | 30                       | 30                            | 90                  | 50                              |
| 10-11                                | 30                       | 30                            | 120                 | 50                              |
| 12                                   | 20*                      | 60                            | 120                 | 50                              |
| 13                                   | 20                       | 10                            | 0                   | 50                              |
| 14                                   | 17** powder              | 40                            | 0                   | 50                              |
| 15-16                                | 20                       | 5                             | 120                 | 50                              |
| 17-18                                | 30                       | 60                            | 120                 | 50                              |
| 19                                   | 20                       | 10                            | 0                   | 50                              |
| 20                                   | 17** powder              | 40                            | 0                   | 50                              |
| 21-22                                | 20                       | 5                             | 120                 | 50                              |
| 23-24                                | 30                       | 60                            | 120                 | 50                              |
| 25-28                                | 40                       | 30                            | 120                 | 50                              |
| 29-35                                | 30                       | 60                            | 120                 | 50                              |
| 36-37                                | 20                       | 120                           | 240                 | 50                              |
| 38                                   | wax powder 2g            | 300                           | 300                 | 50                              |

\* A sorbitol suspension with 2.75% aspartame.

\*\* A powder with a flavour concentration of 25%.

WO 99/44436

PCT/DK99/00108

25

**Example 8**

Coating in tilted kettles of 2kg sugar-free chewing gum cores with a mixture of eucalyptus, menthol, and anethol, encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

| Sorbitol suspension | Amount of dosage | Smoothing out time | Drying time | Number of revolutions |
|---------------------|------------------|--------------------|-------------|-----------------------|
| Dosage No.          | g                | sec.               | sec.        | rpm                   |
| 1                   | 20               | 120                | 120         | 50                    |
| 2                   | 20               | 90                 | 120         | 50                    |
| 3                   | 20               | 60                 | 60          | 50                    |
| 4-9                 | 30               | 30                 | 90          | 50                    |
| 10-11               | 30               | 30                 | 120         | 50                    |
| 12                  | 20*              | 60                 | 120         | 50                    |
| 13                  | 20               | 10                 | 0           | 50                    |
| 14                  | 40**powder       | 40                 | 0           | 50                    |
| 15-16               | 20               | 5                  | 120         | 50                    |
| 17-18               | 30               | 60                 | 120         | 50                    |
| 19                  | 20               | 10                 | 0           | 50                    |
| 20                  | 40**powder       | 40                 | 0           | 50                    |
| 21-22               | 20               | 5                  | 120         | 50                    |
| 23-24               | 30               | 60                 | 120         | 50                    |
| 25-28               | 40               | 30                 | 120         | 50                    |
| 29-35               | 30               | 60                 | 120         | 50                    |
| 36-37               | 20               | 120                | 240         | 50                    |
| 38                  | wax powder 2g    | 300                | 300         | 50                    |

\* A sorbitol suspension with 3.75% aspartame, and 7.5% acesulfame K.

\*\* A powder with a flavour concentration of 24.5%.

WO 99/44436

PCT/DK99/00108

26

**Example 9**

Coating in tilted kettles of 2kg sugar-free chewing gum cores with a mixture of eucalyptus, menthol, and anethol, encapsulated in a 3:1 mixture of hydrogenated rape oil  
5 and carnauba wax.

| Sorbitol<br>suspension<br>Dosage No. | Amount of<br>dosage<br>g | Smoothing<br>out time<br>sec. | Drying time<br>sec. | Number of<br>revolutions<br>rpm |
|--------------------------------------|--------------------------|-------------------------------|---------------------|---------------------------------|
| 1                                    | 20                       | 120                           | 120                 | 50                              |
| 2                                    | 20                       | 90                            | 120                 | 50                              |
| 3                                    | 20                       | 60                            | 60                  | 50                              |
| 4-9                                  | 30                       | 30                            | 90                  | 50                              |
| 10-11                                | 30                       | 30                            | 120                 | 50                              |
| 12                                   | 20*                      | 60                            | 120                 | 50                              |
| 13                                   | 20                       | 10                            | 0                   | 50                              |
| 14                                   | 20**powder               | 40                            | 0                   | 50                              |
| 15-16                                | 20                       | 5                             | 120                 | 50                              |
| 17-18                                | 30                       | 60                            | 120                 | 50                              |
| 19                                   | 20                       | 10                            | 0                   | 50                              |
| 20                                   | 20**powder               | 40                            | 0                   | 50                              |
| 21-22                                | 20                       | 5                             | 120                 | 50                              |
| 23-24                                | 30                       | 60                            | 120                 | 50                              |
| 25-28                                | 40                       | 30                            | 120                 | 50                              |
| 29-35                                | 30                       | 60                            | 120                 | 50                              |
| 36-37                                | 20                       | 120                           | 240                 | 50                              |
| 38                                   | wax powder 2g            | 300                           | 300                 | 50                              |

\* A sorbitol suspension with 3.5% aspartame and 7.5% acesulfame K.

\*\* A powder with a flavour concentration of 24.5%.

WO 99/44436

PCT/DK99/00108

27

## Example 10

Coating in tilted kettles of 2kg sugar-free chewing gum cores with a mixture of liquid eucalyptus, menthol, and anethol, as well as menthol encapsulated in gum arabic.

| Sorbitol<br>suspension<br>Dosage No. | Amount of<br>dosage<br>g | Smoothing<br>out time<br>sec. | Drying<br>time<br>sec. | Number of<br>revolutions<br>rpm |
|--------------------------------------|--------------------------|-------------------------------|------------------------|---------------------------------|
| 1                                    | 20                       | 120                           | 120                    | 50                              |
| 2                                    | 20                       | 90                            | 120                    | 50                              |
| 3                                    | 20                       | 60                            | 60                     | 50                              |
| 4-9                                  | 30                       | 30                            | 90                     | 50                              |
| 10-11                                | 30                       | 30                            | 120                    | 50                              |
| 12                                   | 20*                      | 60                            | 120                    | 50                              |
| 13                                   | 9.9 liquid<br>flavour    | 10                            | 0                      | 50                              |
| 14                                   | 20                       | 40                            | 0                      | 50                              |
| 15-16                                | 20                       | 5                             | 120                    | 50                              |
| 17-18                                | 30                       | 60                            | 120                    | 50                              |
| 19                                   | 20                       | 10                            | 0                      | 50                              |
| 20                                   | 7** powder               | 40                            | 0                      | 50                              |
| 21-22                                | 20                       | 5                             | 120                    | 50                              |
| 23-24                                | 30                       | 60                            | 120                    | 50                              |
| 25-28                                | 40                       | 30                            | 120                    | 50                              |
| 29-35                                | 30                       | 60                            | 120                    | 50                              |
| 36-37                                | 20                       | 120                           | 240                    | 50                              |
| 38                                   | wax powder<br>2g         | 300                           | 300                    | 50                              |

\* A sorbitol suspension with 3.5% aspartame and 7.5% acesulfame K.

\*\* A powder with a flavour concentration of 80%.

WO 99/44436

PCT/DK99/00108

28

**Example 11**

Coating in tilted kettles of 2kg sugar-free chewing gum cores with a mixture of liquid eucalyptus, menthol, anethol, as well as ammonium chloride encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

| Sorbitol<br>suspension<br>Dosage No. | Amount of<br>dosage<br>g | Smoothing<br>out time<br>sec. | Drying time<br>sec. | Number of<br>revolutions<br>rpm |
|--------------------------------------|--------------------------|-------------------------------|---------------------|---------------------------------|
| 1                                    | 20                       | 120                           | 120                 | 50                              |
| 2                                    | 20                       | 90                            | 120                 | 50                              |
| 3                                    | 20                       | 60                            | 60                  | 50                              |
| 4-9                                  | 30                       | 30                            | 90                  | 50                              |
| 10-11                                | 30                       | 30                            | 120                 | 50                              |
| 12                                   | 20*                      | 60                            | 120                 | 50                              |
| 13                                   | 9.9 liquid<br>flavour    | 10                            | 0                   | 50                              |
| 14                                   | 20                       | 40                            | 0                   | 50                              |
| 15                                   | 20                       | 5                             | 120                 | 50                              |
| 16-17                                | 30                       | 60                            | 120                 | 50                              |
| 18                                   | 20                       | 10                            | 0                   | 50                              |
| 19                                   | 40** powder              | 40                            | 0                   | 50                              |
| 20-21                                | 20                       | 5                             | 120                 | 50                              |
| 22                                   | 20                       | 10                            | 0                   | 50                              |
| 23                                   | 40** powder              | 40                            | 0                   | 50                              |
| 24-25                                | 20                       | 5                             | 120                 | 50                              |
| 26-27                                | 30                       | 60                            | 120                 | 50                              |
| 28-30                                | 40                       | 30                            | 120                 | 50                              |
| 31-37                                | 30                       | 60                            | 120                 | 50                              |
| 38-39                                | 20                       | 120                           | 240                 | 50                              |
| 40                                   | wax powder 2g            | 300                           | 300                 | 50                              |

\*A sorbitol suspension with 3.5% aspartame and 7.5% acesulfame K.

\*\*A powder with a ammonium chloride concentration of 30%.



WO 99/44436

PCT/DK99/00108

29

## Example 12

Coating in tilted kettles of 2kg sugar-free chewing gum cores with a mixture of liquid eucalyptus, menthol, and powdered anise, as well as naturally extract of black pepper 5 encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

| Sorbitol<br>suspension<br>Dosage No. | Amount of<br>dosage<br>g | Smoothing<br>out time<br>sec. | Drying<br>time<br>sec. | Number of<br>revolutions<br>rpm |
|--------------------------------------|--------------------------|-------------------------------|------------------------|---------------------------------|
| 1                                    | 20                       | 120                           | 120                    | 50                              |
| 2                                    | 20                       | 90                            | 120                    | 50                              |
| 3                                    | 20                       | 60                            | 60                     | 50                              |
| 4-9                                  | 30                       | 30                            | 90                     | 50                              |
| 10-11                                | 30                       | 30                            | 120                    | 50                              |
| 12                                   | 20                       | 60                            | 120                    | 50                              |
| 13                                   | 20                       | 10                            | 0                      | 50                              |
| 14                                   | 20* powder               | 40                            | 0                      | 50                              |
| 15-16                                | 20                       | 5                             | 120                    | 50                              |
| 17-18                                | 30                       | 60                            | 120                    | 50                              |
| 19                                   | 10 liquid<br>flavour     | 10                            | 0                      | 50                              |
| 20                                   | 20                       | 40                            | 0                      | 50                              |
| 21-22                                | 20                       | 5                             | 120                    | 50                              |
| 23-24                                | 30                       | 60                            | 120                    | 50                              |
| 25-28                                | 40                       | 30                            | 120                    | 50                              |
| 29-35                                | 30                       | 60                            | 120                    | 50                              |
| 36-37                                | 20                       | 120                           | 240                    | 50                              |
| 38                                   | wax powder 2g            | 300                           | 300                    | 50                              |

\* A powder of naturally extract of black pepper in a concentration of 20%.

WO 99/44436

PCT/DK99/00108

30

**Example 13**

Coating in tilted kettles of 2kg sugar-free chewing gum cores with a mixture of liquid eucalyptus, menthol, and powered anise as well as naturally basil extract encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

| Sorbitol<br>suspension<br>Dosage No. | Amount of<br>dosage<br>g | Smoothing out<br>time<br>sec. | Drying time<br>sec. | Number of<br>revolutions<br>rpm |
|--------------------------------------|--------------------------|-------------------------------|---------------------|---------------------------------|
| 1                                    | 20                       | 120                           | 120                 | 50                              |
| 2                                    | 20                       | 90                            | 120                 | 50                              |
| 3                                    | 20                       | 60                            | 60                  | 50                              |
| 4-9                                  | 30                       | 30                            | 90                  | 50                              |
| 10-11                                | 30                       | 30                            | 120                 | 50                              |
| 12                                   | 20                       | 60                            | 120                 | 50                              |
| 13                                   | 20                       | 10                            | 0                   | 50                              |
| 14                                   | 20* <sup>a</sup> powder  | 40                            | 0                   | 50                              |
| 15-16                                | 20                       | 5                             | 120                 | 50                              |
| 17-18                                | 30                       | 60                            | 120                 | 50                              |
| 19                                   | 10 liquid<br>flavour     | 10                            | 0                   | 50                              |
| 20                                   | 20                       | 40                            | 0                   | 50                              |
| 21-22                                | 20                       | 5                             | 120                 | 50                              |
| 23-24                                | 30                       | 60                            | 120                 | 50                              |
| 25-28                                | 40                       | 30                            | 120                 | 50                              |
| 29-35                                | 30                       | 60                            | 120                 | 50                              |
| 36-37                                | 20                       | 120                           | 240                 | 50                              |
| 38                                   | wax powder<br>2g         | 300                           | 300                 | 50                              |

<sup>a</sup> A powder of naturally basil extract in a concentration of 14%.

WO 99/44436

PCT/DK99/00108

31

## Example 14

Coating in tilted kettles of 2kg sugar-free chewing gum cores with a mixture of liquid eucalyptus, menthol, and powdered anise, as well as naturally thyme extract encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

| Sorbitol suspension<br>Dosage No. | Amount of dosage<br>g | Smoothing out time<br>sec. | Drying time<br>sec. | Number of revolutions<br>rpm |
|-----------------------------------|-----------------------|----------------------------|---------------------|------------------------------|
| 1                                 | 20                    | 120                        | 120                 | 50                           |
| 2                                 | 20                    | 90                         | 120                 | 50                           |
| 3                                 | 20                    | 60                         | 60                  | 50                           |
| 4-9                               | 30                    | 30                         | 90                  | 50                           |
| 10-11                             | 30                    | 30                         | 120                 | 50                           |
| 12                                | 20                    | 60                         | 120                 | 50                           |
| 13                                | 20                    | 10                         | 0                   | 50                           |
| 14                                | 20* powder            | 40                         | 0                   | 50                           |
| 15-16                             | 20                    | 5                          | 120                 | 50                           |
| 17-18                             | 30                    | 60                         | 120                 | 50                           |
| 19                                | 10 liquid flavour     | 10                         | 0                   | 50                           |
| 20                                | 20                    | 40                         | 0                   | 50                           |
| 21-22                             | 20                    | 5                          | 120                 | 50                           |
| 23-24                             | 30                    | 60                         | 120                 | 50                           |
| 25-28                             | 40                    | 30                         | 120                 | 50                           |
| 29-35                             | 30                    | 60                         | 120                 | 50                           |
| 36-37                             | 20                    | 120                        | 240                 | 50                           |
| 38                                | wax powder<br>2g      | 300                        | 300                 | 50                           |

\* A powder of naturally thyme extract in a concentration of 15%.

WO 99/44436

PCT/DK99/00108

32

## Example 15

Coating in tilted kettles of 2kg sugar-free chewing gum cores with a mixture of mixture of liquid fruit flavours (orange, Temon, and mango) as well as citric acid 5 encapsulated in a 3:1 mixture of hydrogenated rape oil and carnauba wax.

| Sorbitol<br>suspension<br>Dosage No. | Amount of<br>dosage<br>g | Smoothing out<br>time<br>sec. | Drying time<br>sec. | Number of<br>revolutions<br>rpm |
|--------------------------------------|--------------------------|-------------------------------|---------------------|---------------------------------|
| 1                                    | 20                       | 120                           | 120                 | 50                              |
| 2                                    | 20                       | 90                            | 120                 | 50                              |
| 3                                    | 20                       | 60                            | 60                  | 50                              |
| 4-9                                  | 30                       | 30                            | 90                  | 50                              |
| 10-11                                | 30                       | 30                            | 120                 | 50                              |
| 12                                   | 20*                      | 60                            | 120                 | 50                              |
| 13                                   | 20                       | 10                            | 0                   | 50                              |
| 14                                   | 30**powder               | 40                            | 0                   | 50                              |
| 15-16                                | 20                       | 5                             | 120                 | 50                              |
| 17                                   | 20                       | 10                            | 0                   | 50                              |
| 18                                   | 30**powder               | 40                            | 0                   | 50                              |
| 19-20                                | 20                       | 5                             | 120                 | 50                              |
| 21                                   | 5.7 liquid<br>flavour    | 10                            | 0                   | 50                              |
| 22                                   | 20                       | 40                            | 0                   | 50                              |
| 23-24                                | 20                       | 5                             | 120                 | 50                              |
| 25-26                                | 30                       | 60                            | 120                 | 50                              |
| 27-30                                | 40                       | 30                            | 120                 | 50                              |
| 31-37                                | 30                       | 60                            | 120                 | 50                              |
| 39-40                                | 20                       | 120                           | 240                 | 50                              |
| 41                                   | wax powder<br>2g         | 300                           | 300                 | 50                              |

\* A sorbitol suspension with 7.5% aspartame.

\*\* Encapsulated citric acid in a concentration of 35%.

WO 99/44436

PCT/DK99/00108

33

## Example 16

Coating in tilted kettles of 2kg sugar-free chewing gum cores with a mixture of liquid fruit flavours (orange, lemon, and mango) as well as ascorbic acid encapsulated in a 5 3:1 mixture of hydrogenated rape oil and carnauba wax.

| Sorbitol<br>suspension<br>Dosage No. | Amount of<br>dosage<br>g | Smoothing out<br>time<br>sec. | Drying time<br>sec. | Number of<br>revolutions<br>rpm |
|--------------------------------------|--------------------------|-------------------------------|---------------------|---------------------------------|
| 1                                    | 20                       | 120                           | 120                 | 50                              |
| 2                                    | 20                       | 90                            | 120                 | 50                              |
| 3                                    | 20                       | 60                            | 60                  | 50                              |
| 4-9                                  | 30                       | 30                            | 90                  | 50                              |
| 10-11                                | 30                       | 30                            | 120                 | 50                              |
| 12                                   | 20*                      | 60                            | 120                 | 50                              |
| 13                                   | 20                       | 10                            | 0                   | 50                              |
| 14                                   | 30** powder              | 40                            | 0                   | 50                              |
| 15-16                                | 20                       | 5                             | 120                 | 50                              |
| 17                                   | 20                       | 10                            | 0                   | 50                              |
| 18                                   | 30** powder              | 40                            | 0                   | 50                              |
| 19-20                                | 20                       | 5                             | 120                 | 50                              |
| 21                                   | 5.7 liquid<br>flavour    | 10                            | 0                   | 50                              |
| 22                                   | 20                       | 40                            | 0                   | 50                              |
| 23-24                                | 20                       | 5                             | 120                 | 50                              |
| 25-26                                | 30                       | 60                            | 120                 | 50                              |
| 27-30                                | 40                       | 30                            | 120                 | 50                              |
| 31-37                                | 30                       | 60                            | 120                 | 50                              |
| 39-40                                | 20                       | 120                           | 240                 | 50                              |
| 41                                   | wax powder<br>2g         | 300                           | 300                 | 50                              |

\* A sorbitol suspension with 7.5% aspartame.

\*\* Encapsulated ascorbic acid in a concentration of 60%.

WO 99/44436

PCT/DK99/00108

34

## Example 17

Coating in tilted kettles of 2kg sugar-free chewing gum cores with a mixture of mixture of liquid fruit flavours (orange, lemon, and mango) as well as cooling agent encapsulated in gum arabic.

| Sorbitol<br>suspension<br>Dosage No. | Amount of<br>dosage<br>g | Smoothing out<br>time<br>sec. | Drying time<br>sec. | Number of<br>revolutions<br>rpm |
|--------------------------------------|--------------------------|-------------------------------|---------------------|---------------------------------|
| 1                                    | 20                       | 120                           | 120                 | 50                              |
| 2                                    | 20                       | 90                            | 120                 | 50                              |
| 3                                    | 20                       | 60                            | 60                  | 50                              |
| 4-9                                  | 30                       | 30                            | 90                  | 50                              |
| 10-11                                | 30                       | 30                            | 120                 | 50                              |
| 12                                   | 20*                      | 60                            | 120                 | 50                              |
| 13                                   | 20                       | 10                            | 0                   | 50                              |
| 14                                   | 20** powder              | 40                            | 0                   | 50                              |
| 15-16                                | 20                       | 5                             | 120                 | 50                              |
| 17                                   | 20                       | 10                            | 0                   | 50                              |
| 18                                   | 20                       | 40                            | 0                   | 50                              |
| 19-20                                | 20                       | 5                             | 120                 | 50                              |
| 21                                   | 5.7 liquid<br>flavour    | 10                            | 0                   | 50                              |
| 22                                   | 20                       | 40                            | 0                   | 50                              |
| 23-24                                | 20                       | 5                             | 120                 | 50                              |
| 25-26                                | 30                       | 60                            | 120                 | 50                              |
| 27-30                                | 40                       | 30                            | 120                 | 50                              |
| 31-37                                | 30                       | 60                            | 120                 | 50                              |
| 39-40                                | 20                       | 120                           | 240                 | 50                              |
| 41                                   | wax powder<br>2g         | 300                           | 300                 | 50                              |

\* A sorbitol suspension with 7.5% aspartame.

\*\* Encapsulated cooling agent, "Cooling Flavouring Powder" from International Flavours and Fragrances, Ltd., England, in a concentration of 20%.

WO 99/44436

PCT/DK99/00108

35

**Example 18**

Coating in tilted kettles of 2kg sugar-free chewing gum cores with a mixture of liquid flavours (apple and cinnamon) as well as aspartame encapsulated in a 3:1 mixture of 5 hydrogenated rape oil and carnauba wax.

| Sorbitol<br>suspension<br>Dosage No. | Amount of<br>dosage<br>g | Smoothing out<br>time<br>sec. | Drying time<br>sec. | Number of<br>revolutions<br>rpm |
|--------------------------------------|--------------------------|-------------------------------|---------------------|---------------------------------|
| 1                                    | 20                       | 120                           | 120                 | 50                              |
| 2                                    | 20                       | 90                            | 120                 | 50                              |
| 3                                    | 20                       | 60                            | 60                  | 50                              |
| 4-9                                  | 30                       | 30                            | 90                  | 50                              |
| 10-11                                | 30                       | 30                            | 120                 | 50                              |
| 12                                   | 20                       | 60                            | 120                 | 50                              |
| 13                                   | 20                       | 10                            | 0                   | 50                              |
| 14                                   | 25* powder               | 40                            | 0                   | 50                              |
| 15-16                                | 20                       | 5                             | 120                 | 50                              |
| 17-18                                | 30                       | 60                            | 120                 | 50                              |
| 19                                   | 6.6 liquid<br>flavour    | 10                            | 0                   | 50                              |
| 20                                   | 20                       | 10                            | 0                   | 50                              |
| 21-22                                | 20                       | 40                            | 120                 | 50                              |
| 23-24                                | 30                       | 5                             | 120                 | 50                              |
| 25-28                                | 30                       | 30                            | 120                 | 50                              |
| 29-35                                | 20                       | 60                            | 120                 | 50                              |
| 36-37                                | 30                       | 120                           | 240                 | 50                              |
| 38                                   | wax powder<br>2g         | 300                           | 300                 | 50                              |

\* Encapsulated aspartame in a concentration of 10%.

WO 99/44436

PCT/DK99/00108

36

Test Results

A number of sensory tests were carried out as documentation of the achieved effect by the use of active substances in solid form in the coating of a coated chewing gum.

5

The tests were carried out with 5 to 8 trained tasters per test. The coated chewing gum was served in tasteless plastic cups coded with a randomised three-figure number. There was a 3-minute-break between each product tested, and each product was tested twice.

10

The tests were carried out partly in the form of a measurement of the flavour release as a function of time (time intensity tests), in which the products were tested after 5, 15, 30, 45, 60, 75, 90, 105, 120, 135, 150, 165, 180, 240, 300, 420, and 540 seconds, partly in the form of determination of a taste profile, in which the products

15 were tested in intervals; the initial phase : 0 - 1 minute, the intermediate phase 1 - 3 minute(s), and the end phase 3 - 4 minutes.

Test 1

20 A measurement was carried out of the flavour release as a function of time from a chewing gum coated according to Example 8, i.e. with a mixture of eucalyptus, menthol, and anethol encapsulated in fat and wax. The flavour release from this chewing gum was compared with a chewing gum coated according to Example 3, i.e. with liquid eucalyptus, menthol, and anethol. The result of the test appears from Fig. 25 1 which shows that the use of encapsulated flavour in the coating layer partly results in an extremely high taste onset (taste explosion) during the first 60 seconds, and partly enhances the taste in all chewing phases.

Test 2

30

In this test, measurement of the flavour release as a function of time by the use of the same amount of eucalyptus/menthol/anethol flavour in liquid form (Example 3) and encapsulated in fat and wax (Example 9), respectively, was carried out. The result of the test appears from Fig. 2, which shows that the use of active substance in solid



WO 99/44436

PCT/DK99/00108

37

form provides a strong taste explosion in the initial phase, and a significantly enhanced effect in the first 4-5 minutes can be observed.

### Test 3

5

In this test, the effect of addition of menthol encapsulated in gum arabic to the coating of a chewing gum coated with liquid eucalyptus, menthol, and anethol, cf. Example 10, was examined and compared with a chewing gum coated according to Example 3, i.e. only with liquid eucalyptus, menthol, and anethol.

10

The result of the test is shown in Fig. 3 which shows that addition of encapsulated menthol causes a strong taste explosion in the initial phase and an enhanced taste effect in all the chewing phases.

### 15 Test 4

A stability test was carried out of a chewing gum coated in accordance with Example 18, i.e. coated with apple/cinnamon flavour as well as aspartame encapsulated in fat and wax. By way of comparison, a corresponding chewing gum in which the aspartame was non-encapsulated was tested.

20

The result of the test is shown in Fig. 4 which shows that the chewing gum containing non-encapsulated aspartame loses its stability already after approx. 30 days after coating since it develops a bitter taste. The lack of stability is probably due to a reaction between aspartame and aldehyde-containing flavours. In a corresponding chewing gum with encapsulated aspartame in the coating no change in the taste is observed even after 90 days.

25

Thus, encapsulation of aspartame has a strong stability-improving effect

30

### Test 5

A test was carried out with chewing gum coated according to Example 15, i.e. with a mixture of liquid fruit flavours (orange, lemon, and mango) as well as citric acid

WO 99/44436

PCT/DK99/00108

38

encapsulated in fat and wax in order to determine the taste profile in the initial phase. By way of comparison, a taste profile was recorded for a corresponding chewing gum coated with the same fruit flavours (orange, lemon, and mango), but without encapsulated citric acid in the coating layer. The result of the test is shown in Fig. 5.

5

As will be apparent, a chewing gum with citric acid has a larger taste intensity and stronger citric notes than a corresponding product without citric acid.

#### Test 6

10

A test was carried out in order to determine the taste profile in the initial phase, the intermediate phase, and the end phase, respectively, of a chewing gum coated according to Example 17, i.e. with a mixture of liquid fruit flavours (orange, lemon, and mango) and with and without cooling flavour encapsulated in gum arabic. The result of the test is shown in Figs. 6, 7, and 8 which show that the chewing gum with the cooling agent has a larger taste intensity and stronger citric notes in the initial phase. As is apparent from Figs. 7 and 8, this tendency is maintained in the intermediate phase and in the end phase as well in spite of the fact that the cooling agent was placed in the coating layer only.

20

Thus, the chewing gum according to the invention shows an increased effect of the active substance in all the chewing phases.

#### Test 7

25

In this test the taste profile of a chewing gum coated according to Example 14, i.e. with a mixture of liquid eucalyptus, menthol, and powdered anise as well as natural thyme extract encapsulated in fat and wax, was determined.

30 The use of encapsulated thyme provides the possibility of developing a chewing gum with an entirely new combination of tastes without having to observe the occurrence of discoloration of the coating layer by the use of liquid extract.

WO 99/44436

PCT/DK99/00108

39

Test 8

In this test the taste profile of a chewing gum coated according to Example 12, i.e. with a mixture of liquid eucalyptus, menthol, and powdered anise as well as natural  
5 extract of black pepper encapsulated in fat and wax, was determined. The result of this test is shown in Figs. 12, 13, and 14. In the same way as in test 7, the possibility of creating new combinations of tastes without discoloration of the coating layer is achieved.

- 10 The invention being thus described, it will be obvious that it may be varied in many ways. Such variations are not to be regarded as deviations from the idea and the scope of the invention, and all such modifications as would be obvious to persons skilled in the art, are intended to be included within the scope of the following claims.

WO 99/44436

PCT/DK99/00108

40

Claims

1. A coated chewing gum comprising a core of chewing gum and a coating comprising a coating material and one or more active substance(s), characterised in that  
5 the active substance(s) is/are added in solid form.

2. The coated chewing gum according to claim 1, characterised in that the active substance(s) is/are selected among flavours, acids, salts, high potent sweeteners, and functional substances.

10

3. The coated chewing gum according to claim 1 or 2, characterised in that the flavour is selected among natural, naturally identical or synthetic flavours, and plant extracts.

15 4. The coated chewing gum according to any of the preceding claims wherein the active substance is a natural vegetable flavouring agent.

5. The coated chewing gum according to claim 4 wherein the natural vegetable flavouring agent is selected among fruits and herbs.

20

6. The coated chewing gum according to claim 5 wherein the natural vegetable flavouring agent is selected among coconut, grape fruit, orange, lime, lemon, mandarin, pineapple, strawberry, raspberry, mango, passion fruit, kiwi, apple, pear, peach, apricot, cherry, grapes, banana, cranberry, blueberry, black currant, red  
25 currant, gooseberry, and lingonberry thyme, basil, valerian, fennel, parsley, camomile, tarragon, lavender, dill, cumin, bergamot, sage, aloe vera, spearmint, peppermint, eucalyptus, and mixtures thereof.

7. The coated chewing gum according to any of claims 4-6 wherein the natural  
30 flavouring agent is dried.

WO 99/44436

PCT/DK99/00108

41

8. The coated chewing gum according to claim 7 wherein the water content of the natural flavouring agent is less than 75% by weight, such as less than 60%, preferable less than 40%, more preferred less than 30%, such as less than 25%.

5 9. The coated chewing gum according to claim 7 wherein the water content of the natural flavouring agent is less than 20% by weight, such as less than 15%, more preferred less than 10% such as between 1.5-7%, more preferred between 2-6%.

10. The coated chewing gum according to any of claims 4-9 wherein the natural  
10 flavouring agent is freeze-dried.

11. The coated chewing gum according to any of claims 4-10 wherein the natural flavouring agent is in the form of a powder, slices or pieces or combinations thereof.

15 12. The coated chewing gum according to claim 11 wherein the natural flavouring agent is in a form where the particle size is less than 3mm, such as less than 2mm, more preferred less than 1mm, calculated as the longest dimension of the particle.

13. The coated chewing gum according to claim 11 wherein the natural flavouring  
20 agent is in a form where the particle size is from about 3µ to 2mm, such as from 4µ to 1mm.

14. The coated chewing gum according to any of claims 4-14 wherein the natural flavouring agent comprises seeds from a fruit e.g. from strawberry, blackberry and  
25 raspberry, and which seeds are substantially intact.

15. The coated chewing gum according to any of the preceding claims wherein the natural vegetable flavouring agent also provides the gum formulation with natural colour.

30

16. The coated chewing gum according to claim 3, characterised in that the flavour is selected among peppermint, periwinkle, eucalyptus, spearmint, anethol, menthol, powdered anise, and fruit flavours such as orange, lemon, mango, pineapple, lime,

WO 99/44436

PCT/DK99/00108

42

strawberry, cherry, black currant, blueberry, raspberry, wild berry, cranberry, apple, pear, banana, prune, and plum flavour.

17. The coated chewing gum according to claim 3, characterised in that the plant  
5 extracts are selected among extracts of liquorice, coffee, tea, herbs such as sage, thyme, basil, bergamot, balm, valerian, camomile, lavender, aloe vera, and spices such as pepper, cinnamon, capsicum, paprika, tarragon, fennel, mustard, dill, caraway, parsley, and tomato.

10 18. The coated chewing gum according to claim 2, characterised in that the acids are selected among citric acid, malic acid, tartaric acid, lactic acid, and ascorbic acid.

19. The coated chewing gum according to claim 2, characterised in that the salts  
15 are selected among sodium chloride, potassium chloride, ammonium chloride, sodium bicarbonate, and carbamide.

20. The coated chewing gum according to claim 2, characterised in that the  
sweeteners are selected among aspartame, acesulfame K, saccharin, cyclamate, neohesperidine, thaumatin, glycyrrhizin, and salts thereof, monellin, sucrolase, and  
20 alitame.

21. The coated chewing gum according to claim 2, characterised in that the func-  
tional substances are selected among vitamins, "cooling agents", flavour enhancers, and pharmaceuticals in the coating such as the vitamins A, B, C, D, and E, enzymes,  
25 nicotine, caffeine, acetylsalicylic acid, chlorhexidine, zinc compounds, and antihistamines.

22. The coated chewing gum according to any of the preceding claims wherein the  
active substance(s) is/are in an encapsulated form.

30

23. The coated chewing gum according to any of the preceding claims wherein the  
encapsulated active substance is encapsulated in one or more material(s) selected  
among fatty substances, waxes, gelatine, gum arabic, starch, cellulose, cellulose  
derivatives, shellac, polyvinyl acetate, polyethylene, casein, zein, B cyclodextrine,

WO 99/44436

PCT/DK99/00108

43

silica, yeast cells, and a mixture of the above encapsulation materials, preferably a mixture of fatty substances and carnauba wax.

24. The coated chewing gum according to any of claims 1-23, characterised in that  
5 the coating additionally comprises one or more liquid active substance(s).

25. A method for the preparation of a coated chewing gum according to any of claims 1-24, characterised in that it comprises the following steps:

- 10 1) preparation of a core of chewing gum in a manner known *per se*,
- 2) preparation of a coating suspension, also in a manner known *per se*,
- 3) application of the coating suspension onto the cores of chewing gum  
15 in a manner known *per se*,
- 4) Applying on the coating of one or more active substance(s) in solid form in one or more increment(s) after the application of the coating suspension, and optionally repeating step 3) and 4)  
20
- 5) optionally, application of one or more liquid active substance(s) in one or more increment(s) between the applications of the coating suspension,
- 6) optionally, finally application of a surface layer.  
25

26. The method according to claim 25, characterised in that the coating suspension comprises an aqueous solution of a sugar, a sugar alcohol, an artificial sweetener or mixtures thereof.

30 27. The method according to claim 26, characterised in that the coating suspension comprises an aqueous solution of one or more constituent(s) selected among saccharose, dextrose, sorbitol, xylitol, tagatose, mannitol, maltitol, isomalt, aspartame, acesulfame K, saccharine, cyclamate, taline, and neohesperidine.

WO 99/44436

PCT/DK99/00108

44

28. The method according to any of claims 25-27, characterised in that the coating suspension is applied in approx. 2 to 90 increments, preferably in approximately 30-60 increments.
- 5 29. The method according to any of claims 25-28, characterised in that the active substance(s) present in solid form is/are applied in 1 to 10 increment(s) between the dosages of the coating suspension, preferably 1-4 increment(s).
30. The use of one or more active substance(s) in solid form in the coating of a  
10 coated chewing gum to achieve a fast onset of the effect.
31. The use of one or more active substance(s) in solid form in the coating of a coated chewing gum to achieve a better stability of the active substance.
- 15 32. The use of one or more active substance(s) in solid form in the coating of a coated chewing gum to achieve an increased effect of the active substance(s) in all chewing phases.